

## Main Article

# CLINICAL PROFILE AND SERUM BETA-CAROTENE LEVELS IN ORAL SUBMUCOUS FIBROSIS

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**ABSTRACT:** Clinical profile and serum beta-carotene levels in 100 cases of oral submucous fibrosis (OSMF) were studied. Prevalence of OSMF was noted to be 0.93% of new cases attending ENT OPD. Age of cases varied from 12 to 78 years (mean: 29.09 years) with male-female ratio of 3.3:1 and 80% literacy. Students constituted the single largest group. Burning sensation in oral cavity and inability to open mouth were the chief complaints in 95% cases. In all cases changes in colour of buccal mucosa and palpable fibrous bands in oral cavity were present followed by trismus (99%). About 52% patients were in grade-III OSMF (Journal of Indian Dental Association, 49: 187), oral habits of chewing tobacco, betel nut, etc. were present in 95% patients. Excessive use of chillies was present in 60 and 74% patients were non-vegetarian. Serum beta-carotene levels were below normal in all the three grades of OSMF, lowest being in grade III.

**Key Words:** Secretory otitis media, myringotomy, grommet insertion, outcome

Oral submucous fibrosis (OSMF) is a chronic disease of insidious onset sometimes preceded by vesicle formation or stomatitis and always associated with juxtaepithelial inflammatory reaction and fibroelastic changes of lamina propria with epithelial atrophy. A condition resembling OSMF was described as early as “600” BC by Sushruta and it was named as “VIDARI” having features of progressive narrowing of mouth, depigmentation of oral mucosa and pain on taking food. The present nomenclature was coined by Joshi from Bombay<sup>[1]</sup> and was designated as “submucous fibrosis of palate and pillars”. Overall prevalence of oral submucous fibrosis in India is about 0.5% with a range of 0.2–1.2% in different regions of country. The exact etiology of OSMF is not well understood. Various factors are being studied, such as genetic, autoimmune, nutritional and environmental agents. Among the environmental agents different oral habits are observed like intake of spicy food, chewing of betel nut, betel quid and allied preparations (pan masala, gutka, kharra, etc.). As it is a disease of unknown etiology, till date no satisfactory treatment has been described in literature for OSMF. This study was planned to know the prevalence, predisposing factors and clinical profile of OSMF and to estimate the serum beta-carotene level in cases of OSMF.

## MATERIALS AND METHODS

This study, comprising of 100 cases of oral submucous

fibrosis (OSMF), was carried in the Department of Otorhinolaryngology – Head and Neck Surgery, Mahatma Gandhi Institute of Medical Sciences, Sevagrarn (Wardha), between December 1998 and March 2000.

## Selection of Cases

Diagnosis of all the cases of OSMF attending ENT outdoor was done on clinical grounds (presence of burning sensation, inability to open mouth, inability to protrude tongue, changes in the colour of oral mucosa and presence of palpable fibrous hands in the oral mucosa) and this was confirmed by one of the consultant in the department.

(a) All cases of OSMF attending ENT out patient department were studied. Cases having OSMF alongwith oral or oropharyngeal malignancy were excluded because in these cases tongue protrusion and changes in colour of buccal mucosa could not be measured. Grading of the cases was done according to Bhatt and Dholakia classification.<sup>[2]</sup>

(b) Fifty normal (control) cases aged above 12 years without any oral habit, oral symptoms and disease were taken to find out the average of normal mouth opening, tongue protrusion, palpation of normal buccal mucosa and to establish normal value of serum beta carotene.

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All the selected cases underwent detailed history taking and a thorough general physical examination, otorhinolaryngological examination (particularly oral cavity and throat) and serum beta-carotene estimations. Estimation of serum beta carotene: Blood (5 ml) was collected in EDTA vial from antecubital vein. Plasma was separated by centrifugation at 3000 rpm for 10 min. It was stored at  $-20^{\circ}\text{C}$  and was used to estimate beta-carotene by the method of Bradley and Hornbeck.<sup>[3]</sup> The principle of this method is that proteins are precipitated with ethanol and beta-carotene is extracted into light petroleum. The intensity of yellow colour due to carotene lends to estimation of  $\beta$ -carotene level.

## OBSERVATIONS

The prevalence rate of OSMF was found to be 0.93% in 14,352 new cases. The age group varied between 12 and 78 years (mean age: 29.09 years) There were 77 males and 23 females thus giving predominance of male over female in the ratio of 3.3:1 [Table 1] and 80% patients were educated. There were 91 Hindus and 9 Muslims. Among Hindus maximum number of patients were seen in Kunbi caste (28%) followed by Teli (24%), Bodh (17%) and others (9%). Students constituted the single largest group of patients (26%) followed by farmers (22%), housewives (20%), clerks (12%), shopkeepers (7%), auto-drivers (4%) and others (9%). Among predisposing factors – personal oral habits were present as single habit in 54% patients (chewing tobacco, betal nut, tobacco-like preparation, pan with or without tobacco, smoking) and multiple oral habits were seen in 41%, where as five patients had no personal oral habit. Out of these five patients four patients had history of taking excessive chillies. 46% patients developed OSMF within 1–5 years of these personal oral habits [Table 2]. Excessive use of chillies was present in 60% patients; 74% patients were non-vegetarian, 21% vegetarian and 5% lacto-ovo-vegetarian. Burning sensation in oral cavity and inability to open mouth was present in 95% cases. Other

symptoms are mentioned in decreasing order of frequency in [Table 3]. All cases had changes in colour of buccal mucosa and palpable fibrous bands in oral cavity. Other signs are shown in decreasing order of frequency in [Table 4]. According to Bhatt and Dholakia classification<sup>[2]</sup> 52% patients were in grade-III OSMF followed by 39% in grade II and 9% in grade I. Serum beta-carotene levels were below the normal range for all the grades of OSMF but were lower in grade II (as compared to grade I) and lowest in grade III cases [Table 5].

## DISCUSSION

Prevalence of OSMF in India ranges between 0.02 and 3.2%. In studies done at Sevagram by Marathe<sup>[4]</sup> and Sharma<sup>[5]</sup> the prevalence of OSMF has been reported to be 0.97 and 0.90%, respectively. Our findings fall in between these figures suggest that there is not much change in number of cases of OSMF presenting to our department in last 10–12 years. In our study age ranged from 12 to 78 years, which is consistent with the studies of Rao<sup>[6]</sup> and Marathe<sup>[4]</sup>. Mean age in our study was 29.09 years, which tallies with studies of Sinor et al.<sup>[7]</sup> Majority of our patients (45%) were in 21 to 30-year-age group. The studies done by Golhar et al.<sup>[8]</sup> and Shah and Sharma<sup>[9]</sup> exactly show the same age group as reported by us. Male predominance was observed in our study in the ratio of 3.3:1. Akbar,<sup>[10]</sup> Caniff et al.,<sup>[11]</sup> Marathe<sup>[4]</sup>, Sharma,<sup>[5]</sup> Golhar et al.,<sup>[8]</sup> Deshmukh<sup>[12]</sup> and Gupta<sup>[13]</sup> also showed male predominance. Among Hindus majority of patients were seen in Kunbi caste (28%) followed by Teli (24%). Marathe<sup>[4]</sup> in Sewagram also observed same probably because the population under our study is mainly constituted by these two castes. Majority of our patients were students (26%) and 80% patients were literate indicating that chewing habits are more prevalent in younger age and educated class. Personal oral habits were present in 95% patients. Some workers also noticed OSMF in patients without any oral habit, e.g. 1.81% by Sharma,<sup>[5]</sup> 0.12% by Gupta et al.,<sup>[14]</sup> and 4% by Gupta.<sup>[13]</sup> On the contrary many other workers<sup>[9],[10],[15]</sup> have not encountered any case of OSMF without oral habit. In majority (48%) of our patients (with habit of tobacco or tobacco like preparations) the duration of these habits was up to 2 years and maximum number of patients in this group were in the age range of 20–30 years. Babu et al.<sup>[16]</sup> and Chaudhary<sup>[17]</sup> noted that maximum of OSMF cases due to chewing of pan masala, etc. were below 30 years of age and had started the chewing habits 2–3 years prior to their diagnosis as reported by us. The majority of our cases (78%) presented within first 5 years where as Marathe<sup>[4]</sup> found 46% cases within first 5 years. We reported excessive use of chillies in 60% cases which tallies with study of Deshmukh<sup>[12]</sup> who observed it in 53.8% cases, where as Marathe<sup>[4]</sup> and Sharma<sup>[5]</sup> reported excessive use of chillies in 100%. We observed OSMF amongst non-vegetarian in 74% cases. Marathe,<sup>[4]</sup> Sharma,<sup>[5]</sup>

**Table 1: OSMF - Age and sex-wise distribution of cases**

Age (years)	Males		Females		Total cases
	No.	%	No.	%	
11-20	16	20.8	5	21.7	21
21-30	41	53.3	4	17.4	45
31-40	11	14.3	8	34.8	19
41-50	08	10.3	4	17.3	12
51-60	01	1.3	1	4.4	02
61-70	-	-	-	-	-
71-80	-	-	1	4.4	01
<b>Total</b>	<b>77</b>	<b>100</b>	<b>23</b>	<b>100</b>	<b>100</b>

**Table 2 : OSMF - Personal Oral Habits**

S.No. Personal oral habits Present in			Duration in years					
			No & %	No	Upto 2 %	No	2 to 5 %	>5 No %
<b>I</b>								
N	1	Tobacco/Tobacco	32	18	56.25	11	34.4	03 9.4
G		like preparation alone						
<b>L</b>								
E	2	Betelnut alone	15	06	40	04	26.6	05 33.4
H	3	Pan alone with or without tobacco	05	01	20	01	20	03 60 A
<b>B</b>								
1	4	Smoking alone	02	–	–	02	100	– –
<b>T</b>								
	5	Tobacco + Tobacco like preparation + Betelnut T	23	15	65.2	02	17.4	04 17.4 M
U								
L								
1	6	Tobacco + Tobacco like preparation + smoking	13	09	69.2	02	15.4	02 15.4
P								
L								
E								
<b>H</b>								
A	7	Betelnuts + Smoking + Pan with or without Tobacco	03	01	33.3	02	66.7	– –
B								
I								
T								
<b>S</b>								
	8	Tobacco + Tobacco like preparation + alcohol	02	01	50	01	50	– –

No personal Oral habit in 5 patients. Out of them 4 consumed excessive chillies.

Deshmukh<sup>[12]</sup> and Gupta<sup>[13]</sup> also reported that non-vegetarians are commonly affected. Burning sensation in oral cavity was observed in 95% of our patients. The same percentage has been quoted for burning sensation by Akbar<sup>[10]</sup> and slightly lower figure is mentioned by Sharma,<sup>[5]</sup> whereas Marathe<sup>[4]</sup> reported burning sensation in all cases of OSMF. Other workers have noted this symptom in lower number of patients and lowest percentage reported by Sinha and Jain<sup>[18]</sup> is of 35%. Inability to open mouth was also most common symptom of our patients of OSMF (95%), Marathe<sup>[4]</sup> has noted it in 98% cases. Inability to protrude tongue was

present in 78% of our cases. A wide variation in the occurrence of this symptom is available in the literature. Impairment of taste sensation was complained by 11% of our patients. It was noted in as high as 44% patients by Marathe<sup>4</sup> and 26% by Soni<sup>[19]</sup> by using electrogustometry and in as low as 3.3% cases by Akbar.<sup>[10]</sup> Difficulty in swallowing was complained by 27% of our patients where as only one worker<sup>[4]</sup> has reported it to be present in only 8% of his cases. Excessive salivation was noted in 21% cases and dryness of mouth in 13% by us. Gupta et al.<sup>[20]</sup> reported excessive salivation in 40% and Caniff et al.<sup>[11]</sup> reported

**Table 3: OSMF - Symptoms of patients**

Symptoms	Present		Duration in years					
	Upto 1		1 to 5		>5			
	No	%	No	%	No	%	No	%
Burning sensation in oral cavity	95	60	63.2	28	29.4	07	7.4	
Inability to open mouth	95	75	78.5	15	15.8	05	5.3	
Inability to protrude tongue	78	64	82.0	10	12.9	04	5.1	
Vesiculation in oral cavity	51	45	88.2	05	9.9	01	1.9	
Difficulty in swallowing	27	26	96.3	01	3.7	-	-	
Excessive salivation	21	21	100	-	-	-	-	
Dryness in mouth	13	12	92.4	01	7.6	-	-	
Impairment of taste sensation	11	11	100	-	-	-	-	
Loss of appetite	09	09	100	-	-	-	-	
Swelling in neck	07	07	100	-	-	-	-	
Loss of weight	06	06	100	-	-	-	-	
Referred otalgia	03	03	100	-	-	-	-	
*Others	03	03	100	-	-	-	-	

\*Others include change of voice in 2% and tinnitus in 1%.

dryness of mouth in 34.2%. Change in colour of buccal mucosa (Pallor/Hyperaemia) was observed in all patients (100%). Marathe<sup>[4]</sup> and Sharma<sup>[5]</sup> also observed (100%) involvement of buccal mucosa. We noted palpable fibrous bands in oral cavity in all cases, trismus in 99%, ankyloglossia in 28% and ulceration/vesiculation in 51% cases, which is almost same as observed by Marathe.<sup>[4]</sup> Palatal involvement was seen in 100% by Marathe<sup>[4]</sup> and Sharma,<sup>[5]</sup> 76.9% by Deshmukh<sup>[12]</sup> and we observed its involvement in 71%. Atrophy of uvula was present in 77% in our cases. Deshmukh<sup>[12]</sup> found out involvement of uvula in 88.4%. (There were cases of carcinoma tongue and buccal mucosa which were also observed. by Marathe<sup>[4]</sup> 2 and 1% by Chaturvedi et al.,<sup>[21]</sup> respectively, but these cases were excluded in the present study for the reason mentioned under material and methods). We observed more than half patients (52%) in grade-III OSMF followed by grade II (39%). Our findings are consistent with findings of Phatak.<sup>[22]</sup> Most of the workers<sup>[4],[5],[13],[19]</sup> have encountered higher percentage

**Table 4: OSMF - Clinical Signs**

Clinical Sign	Present (%)
Changes (Erythema, Pallor) in colour of buccal mucosa	100
Palpable fibrous bands in oral cavity	100
Trismus	99
Atrophy of uvula	77
Pallor of soft palate	71
Pallor of hard palate	51
Caries teeth	42
Ankyloglossia	28
Pallor of anterior pillar	26
Pallor of lips	24
Melanoplakia of buccal mucosa	21
Pallor of gums	19
Pallor of tonsils	14
Pallor of gingivo-labial sulcus	13
Pallor of floor of mouth	13
Pallor of posterior pillar	11
Pallor of posterior pharyngeal wall	08
Rhinolalia - aperta	01
Submucosal cleft palate	01

of cases in grade-II OSMF where as Gupta et al.,<sup>[15]</sup> found maximum cases in grade I. The levels of serum beta-carotene were below the normal range for all the grades of OSMF but were lower in grade II (as compared to grade I) and lowest in grade-III cases. Same observation has been reported by Gupta.<sup>[13]</sup>

## SUMMARY AND CONCLUSION

The prevalence of OSMF was noted to be 0.93%. Majority of the patients were in the age range of 21–30 years with male–female ratio of 3.3:1 and 80% literacy. Students constituted the single largest group of patients (26%) burning sensation in oral cavity and inability to open mouth were present in 95% cases. In all cases, changes in colour of buccal mucosa and palpable fibrous bands in oral cavity were

**Table 5: OSMF - Serum Beta carotene levels**

Grade of OSMF	Mean serum beta-carotene levels (∇ g%)
I (n=09)	87.7
II (n=39)	76.3
III (n=52)	69.9

Normal serum beta-carotene level (control cases n=50)= 101.8 ± 10.7 (∇g%)

present followed by trismus (99%). More than half (52%) were in grade III. About 54 patients had single oral habit, whereas multiple habits were present in 41% cases. In 60% cases excessive use of chillies was present. Serum beta-carotene levels were below normal in all the grades of OSMF, lowest being in grade-III cases.

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